II. AMENDMENTS TO THE SPECIFICATION

Please amend the specification as follows in accordance with 37 C.F.R. § 1.121:

At page 4, line 12, please add the following paragraphs:

The first parameter may be obtained by combining the concentration of total TIMP-1 with the concentration of free TIMP-1. The combination is performed by logistic regression analysis.

In an aspect of the invention, at least one second parameter is additionally determined, which represents the concentration of an additional marker different from any form of TIMP-1, in a body fluid sample from the individual. The first parameter representing the concentration of TIMP-1 in a body fluid sample of an individual and the at least one second parameter (different from any form of TIMP-1 in the individual's body fluid sample) may be combined to produce a combined parameter. If the combined parameter is at or beyond a discriminating value, the individual is indicated as having a high likelihood of having cancer. If the combined parameter is not at or beyond the discriminating value, the individual is unlikely to have cancer. In this embodiment, the discriminating value of the combined parameter is a value determined by determining the combined parameter in both a healthy control population and a population with known cancer. Thus, the discriminating value identifies the cancer population with a predetermined specificity or a predetermined sensitivity.

The at least one second parameter may be a parameter representing the concentration of a tumour marker. Such tumour marker may be selected from the group consisting of CEA, soluble u-PAR, cathepsin B, HER2-neu, CA 15-3 and YKL-40.

The combining to generate any combined parameter may be performed by logistic regression analysis.

The method of the invention can be applied to various cancers, such as colorectal cancers and metastatic breast cancer (i.e., breast cancer in patients who

have been previously treated for breast cancer). In one embodiment directed to screening an individual for metastatic breast cancer, the determination of the appropriate parameter is performed at several points in time at intervals, as part of monitoring of a cancer patient after the treatment for primary cancer.